MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNEIL

McNEIL CONSUMER PR(
FORT WASHINGTC

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Approved by FDA on 11/15/93

3140217-X-00-01

FDA use only

A. Patient information

1. Patient Identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	unknown or Date of birth:	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
(x) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event: unknown (mo/day/yr)

4. Date of this report: 10/01/98 (mo/day/yr)

5. Describe event or problem

Consumer alleges that the use of one of our TYLENOL® acetaminophen products was associated with LIVER DAMAGE. According to consumer, she nearly died from misuse of product. No further information was provided.

6. Relevant tests/laboratory data, including dates

unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TYLENOL Analgesic Unknown
#2

2. Dose, frequency & route used

#1 unknown dose, po
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown
#2

4. Diagnosis for use (indication)

#1 unknown
#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 Unknown
#2

7. Exp. date (if known)

#1 Unknown
#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
(x) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 09/28/98

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

LIVER DAMAGE

9. Mfr. report number

1041420A

E. Initial reporter

1. Name, address & phone #

[redacted] 1999

2. Health professional? ( ) Yes ( ) No

3. Occupation

4. Initial reporter also sent report to FDA ( ) Yes ( ) No ( ) Unk

FDA

Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.